

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

Subject: EPA Reg. No.: 7969-GIE/Selontra Rodent Bait
DP Barcode: 433635
PC Code: 202901

From: Marianne Lewis, Biologist
Invertebrate and Vertebrate Branch 3
Registration Division (7508P)

To: Venus Eagle, PM 01
Invertebrate and Vertebrate Branch 3
Registration Division (7508P)

Applicant: BASF Corp
26 Davis Dr., P.O. Box 13528
Research Triangle Park, NC 27709-3528

Marianne Lewis
scr *12/27/16*

FORMULATION FROM EPA Reg. No. 7969-GIE LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Cholecalciferol:	0.075%
<u>Inert Ingredient(s):</u>	<u>99.925%</u>
Total	100.000%

BACKGROUND: The registrant has submitted new acute toxicity studies to support the registration of their new product, EPA Reg. No. 7969-GIE. The MRID's are as follows: 496675-10 (81-1), 496675-11 (81-2), 496675-12 (81-3), 496675-13 (81-4), 496675-14 (81-5), 496675-15 (81-6). The studies were conducted by Product Safety Labs. The test material used in each of the studies was the subject product, referred to in the studies as BAS 410 06 I, which is the US Formulation.

RECOMMENDATIONS:

- The acute toxicity studies submitted are acceptable to support the registration of EPA Reg. No. 7969-GIE.

The acute toxicity profile for EPA Reg. No. 7969-GIE is currently:

Acute Oral	IV	Acceptable
Acute Dermal	IV	Acceptable
Acute Inhalation	III	Acceptable
Primary Eye	IV	Acceptable
Primary Dermal	IV	Acceptable
Skin Sensitization	skin sensitizer	Acceptable

NOTE: The acute toxicity requirements have been satisfied for the subject product.

DATA REVIEW FOR ACUTE ORAL TOXICITY (§81-1, 870.1100)

Product Manager: Venus Eagle, PM 01
MRID No.: 496675-10

Reviewer: Marianne Lewis
Study Completion Date: 9/11/2015
Report No.: 41222

Testing Facility: Product Safety Labs
Author: Jennifer Durando

Quality Assurance (40 CFR §160.12): Included

Test Material: BAS 410 06 I, 30% w/w solution in distilled water – other mixtures were too viscous to be administered properly

Species: Sprague Dawley rat

Age: young adult

Weight: females = 160 – 176 g

Source: SAGE Labs

Conclusion: Up and Down Method

1. **LD₅₀ (mg/kg):** > 5000 mg/kg

2. **Toxicity Category:** IV

Classification: Acceptable

Procedure (Deviations from §81-1): none

Results:

Limit Dose

Test Sequence	Animal Id	Dose Level (mg/kg)	Short term outcome	Long term outcome
1	3101	5000	S	S
2	3102	5000	S	S
3	3103	5000	S	S

S = survival; D = death

Observations: All were active and healthy throughout the test period

Gross Necropsy: No gross abnormalities were noted

DATA REVIEW FOR ACUTE DERMAL TOXICITY (§81-2, 870.1100)

Product Manager: Venus Eagle, PM 01
MRID No.: 496675-11

Reviewer: Marianne Lewis
Study Completion Date: 9/11/2015
Report No.: 41223

Testing Facility: Product Safety Labs
Author: J. Durando

Quality Assurance (40 CFR §160.12): Included

Test Material: BAS 410 06 I

Species: Sprague Dawley derived albino rat
Weight: males = 256-284 g; females = 183-195 g
Age: young adult
Source: SAGE Labs

Summary:

1. **LD₅₀ (mg/kg):** > 5000 mg/kg

2. **Toxicity Category:** IV

Classification: Acceptable

Procedure (Deviations From §81-2): none

Results: **Reported Mortality**

Dosage (mg/kg)	(number deaths/number tested)		
	Males	Females	Combined
5000	0/5	0/5	0/10

Observations: Twenty four hours prior to application of the test material the dorsal area and trunks were clipped free of hair. The test material was prepared as a dry paste, 75% w/w in distilled water. The test material was then applied to a 2 x 3 inch, 4-ply gauze pad which was placed on the intact test site - 2 x 3 inches (approx. 10% of the total body surface. The pads and trunks were wrapped with a 3 inch Durapore tape. After 24 hours, the wraps and pads were removed and the test sites were gently cleansed w/3% soap solution.

All were active and healthy throughout study, one female had slight alopecia on top of the head from day 4 through day 14.

Gross Necropsy Findings: No observable abnormalities were noted.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3, 870.1300)

Product Manager: Venus Eagle, PM 01
MRID No.: 496675-12

Reviewer: Marianne Lewis
Study Completion Date: 9/11/2015
Report No.: 41224

Testing Facility: Product Safety Labs
Author: J. Durando

Quality Assurance (40 CFR §160.12): Included

Test Material: BAS 410 06 I, 20% w/w mixture in distilled water

Species: Sprague Dawley derived albino rat
Weight: males = 330-371 g; females = 214-245 g
Age: young adult
Source: SAGE Labs

Summary:

- LC₅₀ (mg/L):** > 1.78 mg/L (maximum attainable concentration)
- MMAD:** 2.14 µm **GSD:** 2.26
- Tox. Category:** III **Classification:** Acceptable

Procedure (Deviation From §81-3): none

Results: Reported Mortality

Exposure Concentration	(number deaths/number tested)		
	Males	Females	combined
1.78 mg/L	0/5	0/5	0/10

Chamber Atmosphere		
Dose Level mg/L	MMAD	GSD
1.78	2.14 µm	2.26
	2.07 µm	2.28

Chamber	Dose Level mg/L
---------	-----------------

Environment	5.04
Chamber Volume	28 L (nose only)
Airflow (L/min)	50
Temperature (°C)	23-24
Relative Humidity %	47-81

Clinical Observations: All lost weight initially but gained weight by day 3 through to end of study. Irregular breathing lasting through day 1. All active and healthy from day 2 until end of study.

Gross Necropsy Findings: No observable abnormalities noted.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: Venus Eagle, PM 01
MRID No.: 496675-13

Reviewer: Marianne Lewis
Study Completion Date: 9/11/2015
Report No.: 41225

Testing Facility: Product Safety Labs
Author: J. Durando

Quality Assurance (40 CFR §160.12): Included

Test Material: BAS 410 06 I

Dosage: 0.1 mL (0.1 g – test material ground in coffee mill prior to instillation)

Species: New Zealand albino rabbit

Sex: 3 females

Weight: 1963 – 2307 g

Age: young adult

Source: Robinson Services, Inc.

Summary:

Toxicity Category: IV

Classification: Acceptable

Procedure (Deviations From §81-4): none

Results:

Observations	(number "positive"/number tested)					
	Hours				Days	
	1	24	48	72		
Corneal Opacity	0/3	0/3	0/3	0/3		
Iris	0/3	0/3	0/3	0/3		
Conjunctivae						
Redness	2/3	0/3	0/3	0/3		
Chemosis	1/3	0/3	0/3	0/3		

Prior to instillation, a systemic analgesic (Buprenorphine SR) was administered to relieve potential discomfort associated with eye irritation, 0.1 mg/kg of body weight of analgesic was administered to maintain therapeutic blood levels. 1-2 drops of ocular anesthetic (Tetracaine Hydrochloride Ophthalmic Solution USP, 0.5%) placed into treated and control eye of each animal.

Redness & Chemosis scores were '1' which are not considered positive.

All animals were active and healthy for the duration of the study.

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: Venus Eagle, PM 01
MRID No.: 496675-14

Reviewer: Marianne Lewis
Study Completion Date: 9/11/2015
Report No.: 41226

Testing Facility: Product Safety Labs
Author: J. Durando

Quality Assurance (40 CFR §160.12): Included

Test Material: BAS 410 06 I

Dosage: 0.5 mL
Species: New Zealand albino rabbit
Age: young adult
Sex: 1 male, 2 females
Weight: male = 2591 g; females = 2275 – 2443 g
Source: Robinson Services Inc

Summary:

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

Procedure (Deviations From §81-5): none

Results: Twenty-four hours prior to application of the test material the dorsal area and trunks were clipped free of hair. The test material was applied as a dry paste (75% w/w mixture in distilled water) to a 1 x 1 inch, 4-ply gauze patch which was applied to the 6 cm² intact dose site. The pad and trunk of each animal were wrapped with semi-occlusive 3-inch Micropore tape. Elizabethan collars were placed on each rabbit. After 4 hours the pads and wrappings were removed and the test sites were cleansed with 3% soap solution and water.

At 1 hr, 1/3 exhibited very slight erythema. From 24 to 48 hrs., 1/3 very slight erythema. At 72 hrs, all irritation had cleared in all.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: Venus Eagle, PM 01
MRID No.: 496675-15

Reviewer: Marianne Lewis
Study Completion Date: 9/11/2015
Report No.: 41227

Testing Facility: Product Safety Labs
Author: J. Durando

Quality Assurance (40 CFR §160.12): Included

Test Material: BAS 410 06 I

Positive Control Material: alpha-hexylcinnamaldehyde (HCA) conducted 3/24/15 – 4/23/15

Species: Hartley albino guinea pig
Weight: males = 322 - 391 g
Age: young adult
Source: Hilltop Lab Animals, Inc.

Method: Buehler

Summary:

1. **This Product is a skin sensitizer**
2. **Classification:** Acceptable

Procedure (Deviation From §81-6): none

Procedure:

A group of animals were used to determine the highest non-irritating concentration (HNIC) of the test substance prior to the challenge dose. The HNIC for the test substance was determined to be 90% w/w mixture in mineral oil.

The test animals were induced with 0.4 g of 90% w/w ground test material in mineral oil once a week for three weeks using a Hill Top Chamber. Twenty-four hours after each induction dose the animals were scored for irritation. Two weeks after the last induction dose, 0.4 g of 90% w/w of ground test material in mineral oil was used to challenge the test animals. Twenty-four and 48 hours after the challenge the animals were evaluated for sensitization.

A group of ten animals were used as naive controls. These animals received only the challenge doses of the test material.

Results:

Twenty-four hours after the first induction dose for the test material-induced animals, 1/20 exhibited very faint erythema. After the second induction dose, none exhibited any reactions.

After the third induction dose, none exhibited any reactions.

Twenty-four hours after challenge, 5/20 test material-induced animals exhibited very faint erythema (20% more reacted over induction phase).

At 24 hours, in the naive control group of animals challenged with the test material, none exhibited any reactions.

LABELING:

ID #: 007969-GIE SELONTRA RODENT BAIT

SIGNAL WORD: CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Harmful if inhaled. Avoid breathing dust. Wear long sleeved shirt, long pants, shoes, and socks. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

FIRST AID:

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.